Revised February 16, 1989

General Questions and Answers About Reporting Under the TSCA § 8(d) Health and Safety Study Reporting Rule 40 CFR Part 716

1. What type of monitoring reports must be submitted?

Answer

Monitoring efforts that attempt to define exposure levels of those workers associated with the manufacture or processing of a subject chemical must be submitted if the data are analyzed and their meaning discussed in the study report. An example is a company that monitors exposure of workers involved in the manufacture of toluene and presents the results in a report that may discuss the following: the number of workers, their job descriptions, how the monitoring was done, and what data were obtained.

However, daily or routine monitoring data, even if they are tabulated, do not have to be submitted if the report merely confirms that permissible levels of a chemical have or have not been exceeded (e.g., a one page memorandum that states that monitoring was done on a particular day and results indicate measured concentrations were within government or industry limits).

2. My company does overall operations reports that sometimes have portions dedicated to particular 8(d) chemicals. How does the definition of "study", as applied to monitoring data, relate to these reports?

Answer

The relevant portions of these reports should be submitted, not the whole report. Also, the portions should be submitted only if they are "studies" which include analysis of summarized, tabulated, or aggregated data (see question 1). The rule does not require the submission of raw data or reports of raw data, but rather limits submission to documents in which the data have been studied and their meaning analyzed and discussed.

3. We monitor an effluent stream for the concentration of a group (class) of chemicals. The group contains a listed chemical. Assuming that the monitoring effort fits the description of a study, must it be submitted?

Answer

No. § 716.20(a)(8) exempts this type of study when the data are not analyzed to determine the exposure or concentration of the substance(s) listed in § 716.120.

4. We monitor for VOC (volatile organic compounds). One of the hydrocarbons is a listed substance. Assuming that the monitoring effort fits the description of a study, must it be submitted?

Answer

No. § 716.20(a)(8) exempts this type of study when the data are not analyzed to determine the exposure or concentration of the substance(s) listed in § 716.120.

5. Must human skin patch tests on mixtures be submitted?

Answer

No. § 716.20(a)(6) exempts dermal sensitization studies on mixtures containing listed substances.

6. A listed chemical is added to a test substance which is also listed. The sole purpose of the added chemical is to introduce the test substance into a testing system. Should the resulting studies be reported as studies of the test substance or of the mixture formed for the purpose of performing the studies?

Answer

Companies should consider the studies as studies of the tested chemical substance, not as studies of the mixture formed for testing purposes.

7. Must companies submit the underlying data and the protocol to a health and safety study?

Answer

§ 716.10(a)(4) exempts the submission of underlying data. These data can be requested at a later date. The protocol or materials and methods section of the study, including appended material, must not be deleted, since this is part of the study. However, if a particular method or procedure is referenced e.g.,"Phosphate

and silicate were analyzed calorimetrically by standard techniques (7)", the referenced material is not required to be submitted initially.

8. Certain additives used in our products contain one or two section 8(d) listed substances as subcomponents. We have thousands of studies on these products which are retrievable by an index system that would not ordinarily retrieve by subcomponent of an additive; thus to find a study of a product mixture with an additive containing one of the listed substances we would have to individually examine over a thousand studies. How can we be in compliance with the requirement of § 716.10(a) to submit copies of studies of mixtures that are known to contain a substance listed in § 716.120?

Answer

The answer to the problem is provided by the language of § 716.25 of the rule which says that "the scope of a person's responsibility to search records is limited to records where the required information is ordinarily kept, and to records kept by the person's individual employees whose assigned duty is to advise the person on the health and environmental effects of chemicals." The company indicated that if they were doing the search for their own business purposes they would design their search to recover records retrievable by chemical name through their index system and to recover studies of mixtures where the mixture has the chemical in which they are interested (in this case the chemical listed in the rule) as a specifically named ingredient. We consider this to be an adequate search within the intent of the rule language quoted above. Because of the number or studies involved, we would regard the study by study examination that was contemplated as uncalled for under § 716.25.

9. An 8(d) listed chemical is used as an additive to stabilize another substance which is marketed. Company indexing systems for studies would ordinarily record and retrieve the studies on the chemical substance, ont studies of the additive. Does the company have an obligation to go through all its studies to see if an 8(d) listed chemical may have been present as an additive?

Answer

The section 8(d) rule requires only a reasonable search of files as they are kept and retrieved in the ordinary course of business; therefore the company will comply with the rule by searching by its normal retrieval index (see question 8). Furthermore, we have defined (§ 716.45) studies of a chemical

substance containing a stabilizer as studies of the substance, not as studies of the stabilizer plus the substance.

10. What type of file search for studies on mixtures will satisfy the requirements of the rule? The company indicated that it would be difficult to search for studies on mixtures because the files in many instances are accessed by product name, not individual components. Thus, it would be necessary to determine product compositions so that studies on the products (mixtures) could be retrieved. Also, it would be necessary to determine if the product formulations have been changed in the past because older studies might be on mixtures that do not contain the listed substances while the products as presently formulated do.

Answer

An alternative to the file search described in question 8 could consist of an examination of non-exempt (§ 716.20(a)(6)) product studies (subchronic, chronic, environmental, etc.) in their files by scanning the study and appended formulation information, or information known to the searcher, to see if listed substances are identified. If the substances can not be identified, no other search is required.

11. Should the results of a clinical test on an employee be submitted? Should reports that characterize and discuss the implications of blood levels of a chemical in a group of workers be submitted?

Answer

An individual's test results that would appear in a medical record should not be submitted (see § 716.10(a)(4)), while the report detailing blood levels should be submitted since it is a study of exposure to the workforce and has implications beyond the results of a single blood level determination.

12. Many times we will hire a testing laboratory to conduct a series of tests on a chemical or undertake a series of monitoring efforts in and around a production site. According to § 716.60(b)(1), we must inform EPA of any study initiated by or for us within 30 days of initiation of the study. However, since the laboratory will start the tests over a period of months, it may not be possible for us to learn the starting date for each test without a considerable amount of coordination between the lab, the site (if monitoring studies are being done), and the corporate office responsible for submitting the list to EPA. We are

concerned that we may not learn the study initiation date early enough to be in compliance with the rule.

Answer

It is permissible to notify EPA when a company enters into a contract (initiates a testing plan) with a lab for testing or monitoring, not just when the testing is physically initiated. This will provide EPA with a list of upcoming testing and approximate starting dates for the tests.

13. Should we submit lists of studies known to us, but not in our possession, if we cannot identify the person possessing the study?

Answer

No. Only a complete listing submission under § 716.35(a)(3) must be submitted, i.e., name of study and probable location of person in possession (name of the company).

14. Must companies list studies initiated by or in the possession of foreign subsidiaries or parents? Also, must copies of studies on chemicals manufactured by foreign subsidiaries be submitted?

Answer

Companies are not required to acquire copies of studies from their foreign subsidiaries. Companies are required , however, to list studies known to them, but not in their possession, if they know that it will not be submitted by the person who conducted or initiated the study (§ 716.35(a)(3)). Companies do not have to search for studies on chemicals manufactured by foreign subsidiaries (§ 716.30(a)).

15. Must companies submit lists of studies known to them when the persons known to possess the studies reside outside the U.S.?

Answer

Yes. The rule makes no distinction concerning the physical location of the persons known to possess the studies. If the studies will not be submitted by the person who conducted or initiated the study, then they must be listed (see § 716.20(a)(4)).

16. Must U.S. companies search foreign plant sites for studies on chemicals that are manufactured or processed at U.S. plant sites?

Answer

No. Only sites in the U.S. must be searched.

17. Must Material Safety Data Sheets (MSDS) be submitted?

Answer

If persons can determine that the originator of the MSDS (the manufacturer or processor of the substance) will submit the studies cited in the MSDS (see § 716.20(a)(4)), then the studies referenced in the MSDS need not be listed.

18. Are listed chemicals that are used for cleaning metal parts or other articles considered to be processed under TSCA?

Answer

A listed substance used only to clean metal parts is not considered to be processed under TSCA.

19. Are laboratory chemicals that are used to test manufactured chemicals considered to be processed under TSCA?

Answer

No. Since these substances are not prepared for distribution in commerce, they are not processed under TSCA.

20. Many refinery streams contain section 8(d) listed chemicals as natural components. For instance, "sweetened naphtha, 6474-87-3" contains "hexane, 110-54-3." If hexane is subject to section 8(d), must companies submit studies on naphtha as a mixture containing hexane? Similarly, petroleum contains toluene. Should studies on petroleum be submitted?

Answer

No. For purposes of reporting under the section 8(d) rule, studies on refinery streams will not have to be submitted if natural components of the stream are subject to the section 8(d) rule. For instance, companies would not have to submit studies on petroleum, which contains toluene a listed section 8(d)

substance. However, if a company separately produces toluene, then any health and safety studies on toluene must be submitted. Many refinery streams are listed on the TSCA Inventory as chemical substances. Studies on a stream would be submitted only if the stream becomes subject to section 8(d).

21. Gasoline contains toluene. Many times toluene is present in the gasoline mixture because it is a component of a refinery stream (listed on TSCA Inventory as a substance) that was added to the gasoline. However, occasionally toluene (subject to the rule) is added directly to the gasoline to boost the octane rating. Since the section 8(d) rule requires the submission of studies on mixtures containing listed substances (toluene), must all studies on gasoline be submitted?

Answer

No. Studies on gasoline need only be submitted when it can be determined through a reasonable file search that the toluene was added directly to the gasoline.

22. Should studies on purchased catalysts and process solvents be submitted if the catalysts and solvents are used to produce products sold?

Answer

No. Catalysts and process solvents are used. Only studies on substances manufactured or processed for distribution in commerce must be submitted. Studies on manufactured or processed chemicals containing 8(d) listed substances as impurities are not required to be submitted (§ 716.20(a)(9)).

23. Must design or modeling studies and performance studies to assess the operation of an existing treatment plant or pollution-control unit be submitted?

Answer

Design or modeling studies done for the construction of equipment or plants need not be submitted. However, assessments of actual human or environmental exposure for instance, or projections of exposure based on models (air dispersion, soil transport models, etc.) must be submitted. For instance, many studies employ models that help estimate the carcinogenic potential of a substance given various levels of exposure to the substance. Studies done to determine the efficiency of a treatment plant, such as chemical degradation, are not required to be submitted.

QUESTIONS AND ANSWERS: APPLICABILITY OF TSCA SECTION 8(d) MODEL HEALTH AND SAFETY DATA REPORTING RULE (40 CFR PART 716) TO MODELING STUDIES

The TSCA section 8(d) Model Health and Safety Data Reporting Rule (40 CFR Part 716) sets forth requirements for the submission of lists and copies of health and safety studies on chemical substances and mixtures (substances) selected for priority consideration testing rules under section 4(a) of TSCA and on other substances for which EPA requires health and safety information. The rule requires manufacturers, importers, and processors to submit to EPA unpublished health and safety studies conducted on the substances listed at 40 CFR 716.120. Generally, any information or data that relates to, or bears on, the effects of a listed substance on health or the environment is considered a health and safety study (sec. 716.3 - "health and safety study" definition). Contained within the definition of health and safety study are "assessments of human and environmental exposure." Falling within this category of studies are certain modeling studies in which concentrations or quantities of a substance to which humans or the environment are likely to be exposed are estimated by applying mathematical models of chemical distribution, transport and/or fate to measured or estimated data on chemical releases, conditions of release, and relevant environmental conditions such as wind speed and direction. The purpose of this document is to clarify the applicability of the TSCA section 8(d) Model Health and Safety Data Reporting Rule to such modeling studies.

Generally, under the TSCA section 8(d) Model Health and Safety Data Reporting Rule, the Agency does not require the reporting of modeling studies which employ data-input scenarios that are unlikely to occur under normal operating conditions. Modeling studies which estimate actual or reasonably likely environmental or human exposures are required to be reported. Specific questions with answers follow:

1. We frequently conduct modeling studies in which conservative or worst case assumptions are used to ascertain if our emissions of a specific chemical could possibly to be of concern. For example, we will model the release of the chemical under conditions in which the wind is assumed to blow in one direction all of the time, and we estimate the maximum chemical concentration that would occur (at any distance) under various possible combinations of wind speed and atmospheric stability conditions. Are such studies reportable?

Answer

No. Modeling studies in which conservative or worst case assumptions (i.e., assumptions not reasonably likely under normal operating conditions) are used, as are often conducted in the early phases of modeling analyses, are not reportable under the section 8(d) model rule.

2. My company estimates environmental concentrations beyond our plant boundaries for both fugitive and stack releases. Because we do not actually measure stack emissions, these estimates are based on stack parameters for our facility. Furthermore, we don't have detailed information regarding which pipe valves, fittings, etc. are leaking. We therefore attempt to estimate process losses and assume that this figure represents fugitive emissions over an approximate plant area. Should such modeling studies be submitted even though not all of the input data are actually measured or known?

Answer

If the modeling exercise uses your best estimates of emission quantities and conditions, and provides you with realistic estimate of actually anticipated environmental concentrations, then this modeling study should be reported under the section 8(d) model rule.

3. In support of local emergency planning committees, as well as for our own purposes, we conduct vulnerability analyses for extremely hazardous or other substances. Should we report these studies under the section 8(d) model rule?

Answer

No. These analyses are not based on actual or likely exposure scenarios.

4. In designing and developing new models, our scientists may test the model by conducting simulations using a chemical which is listed at 40 CFR 716.120 (substances subject to reporting under section 8(d)). Is the model development paper therefore reportable?

Answer

If the use of the data is strictly illustrative and the modeling results are not estimates of expected human or environmental exposures under normal operating conditions, the model

development study need not be reported under the section 8(d) model rule. However, reporting is required if the new model has been applied to develop estimates of actual human or environmental exposures under normal operating conditions.

5. Occasionally we prepare fact sheets containing information derived through model analyses. Are these fact sheets reportable?

Answer

No, there is no need to report a summary of other documents. However, the other documents used to prepare the fact sheets may be reportable studies.

6. My company occasionally conducts modeling on 8(d) listed chemicals. The results are reflected in computer printouts or hand-written calculations by our statisticians. While our management may be informed of these results informally, no report is ever prepared. Would the computer printouts, hand-written notes or internal communications contained in our files be considered reportable studies?

Answer

No. Reporting is not required unless modeling results are incorporated in a "copy of study" as defined in EPA's rule. See 40 CFR § 716.3. Such a document should have the attributes of a scientific report -- i.e., it should contain a description of the methodology, tabulation of the data, and a summary of the conclusions. Modeling results which are not incorporated in such a report are not submittable to EPA. For example, computer printouts, hand-written calculations, laboratory notebooks, or informal management summaries would not be reportable even if they are based on a standard modeling protocol kept in a separate portion of the company's files.

7. My company manufactures substances which are subject to reporting under section 313 of the Emergency Planning and community Right-to-Know Act (EPCRA) and are also listed in EPA's model section 8(d) rule. Are the toxic chemical release forms (Form Rs) which we submit to EPA under section 313 reportable studies for purposes of section 8(d)? Must we submit the workpapers and calculations underlying the estimates included in these forms?

Answer

No. The Form Rs simply estimate the quantities of listed chemicals which are released into the environment at company boundaries. They do not attempt to determine environmental exposure levels. For this reason, Form Rs do not constitute "assessments of human health and environmental exposure." The same conclusion applies to the backup materials for Form Rs. These documents likewise tabulate, calculate, or estimate release levels of listed chemicals but do not use this information to determine or estimate the concentrations of these chemicals present in the environment.

8. In order to obtain air permits or to evaluate possible process modifications, my company uses modeling techniques to estimate the environmental concentrations of listed chemicals that might be associated with releases from plants or production units that are planned but are not yet in operation. Must the results of such modeling be submitted under section 8(d)?

Answer

No. Modeling studies performed in anticipation of the construction of equipment or plants need not be submitted because they do not estimate actual or reasonably likely levels for existing environmental releases.

9. The section 8(d) model rule requires that EPA be notified of health and safety studies initiated by or for a subject company subsequent to the initial reporting deadline. When is a company considered to have initiated a modeling study?

Answer

As stated in question 1, screening level modeling studies frequently utilize conservative or worst case assumptions and in such cases are not reportable under the 8(d) model rule. However, when a company contracts for or begins work on a modeling study in which the objective is to develop reasonable estimates of actual human or environmental exposure under normal operating conditions, such initiation must be reported to EPA within 30 days. If the final modeling report will be available and is submitted to EPA within 30 days of study initiation, separate notice of initiation is not required.

July 27, 1989

ADDENDUM #1 TO GENERAL 8(d) Q & A DATED FEBRUARY 16, 1989

GENERAL QUESTIONS AND ANSWERS REGARDING REPORTING
UNDER THE TSCA SECTION 8(d) HEALTH AND SAFETY STUDY REPORTING RULE

(40 CFR PART 716)

1. My company has on its property certain 8(d) listed substances which we do not, nor have we ever proposed to, manufacture, import, or process. Asbestos pipe insulation is an example of such an 8(d) listed substance and which is occasionally the subject of workplace monitoring. Is my company responsible for reporting the health studies generated from such monitoring efforts?

Answer

No. A company is required to report on a specific listed substance or mixture only if it has either proposed to manufacture, import, or process the specific listed substance or mixture, or has manufactured, imported, or processed the specific listed substance or mixture -- per the requirements and limitations set forth at 40 CFR 716.5. Since no such activity has been initiated or proposed by your company for the referenced specific listed substances, no reporting is required.

2. Must reports which are solely the products of published literature searches be submitted under the 8(d) model rule (40 CFR Part 716)?

Answer

No. Reports which merely describe, summarize, etc. the existing published literature on a given topic need not be submitted.

3. My company manufactures substances which are subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and are also listed in EPA's model section 8(d) rule. Are the toxic chemical release forms (Form Rs) which we submit to EPA under section 313 reportable studies for purposes of section 8(d)? Must we submit the workpapers and calculations underlying the estimates included in these forms?

Answer

No. The Form Rs simply estimate the quantities of listed chemicals which are released into the environment at company boundaries. They do not attempt to determine environmental

exposure levels. For this reason, Form Rs do not constitute "assessments of human health and environmental exposure." The same conclusion applies to the backup materials for Form Rs. These documents likewise tabulate, calculate, or estimate release levels of listed chemicals but do not use this information to determine or estimate the concentrations of these chemicals present in the environment.

4. My company has initiated a study to determine the acute ecotoxicity of the effluent at our main plant. No chemical or mixture (substance) listed on the 8(d) model rule has been specifically identified as being in the effluent, although there are such substances used (e.g., processed) in one or more processes at the site and likely to be a component of the effluent. Section 716.10 of the 8(d) model rule states that studies of mixtures known to contain substances listed in section 716.120 are reportable except for certain exempted studies. Assuming that none of the exemptions at § 716.20 (especially paragraphs (a) (6), (7), and (8)) apply to the initiated study, when will a company be judged to have knowledge that a mixture contains a listed substance thus rendering the study reportable under the 8(d) model rule?

Answer

A company will be considered to have knowledge that a mixture contains a listed substance when an employee of the company has actual knowledge or, by the nature of his/her position or responsibility within the company should have knowledge, that a listed substance is present in the mixture. For example, if a chemical engineer employed by a company which has initiated a study as described above could reasonably determine, based upon an informal evaluation of the processes involved, that the tested effluent contains an 8(d) listed chemical substance, the company will be considered to have knowledge and be subject to the reporting requirements in 40 CFR Part 716. Any submission made to EPA pursuant to this rule must identify the 8(d) listed substance(s) which triggered the reporting requirement (8(d) listed substances known, per the above discussion, to be present in the effluent).

Note that a different reporting threshold applies for monitoring data on mixtures containing 8(d) substances. Per § 716.20(a)(8), monitoring data on mixtures known to contain one or more listed substances do not have to be reported unless the data are analyzed to determine the exposure or concentration levels of the listed substances. Additionally, per § 716.20(a)(6), certain types of mixture studies are exempted from reporting. (See questions 8 & 9 of the Q & A document dated February 16, 1989 for related issues regarding reporting mixture studies.)

November 1, 1989

Questions and Answers: Applicability of TSCA Section 8(d) Model Health and Safety Data Reporting Rule (40 CFR Part 716) to Monitoring Studies

The purpose of this guidance document is to clarify the applicability of the TSCA Section 8(d) Model Health and Safety Data Reporting Rule to workplace and environmental monitoring studies. The Section 8(d) Model Rule (40 CFR Part 716) sets forth requirements for the submission of lists and copies of health and safety studies on chemical substances and mixtures for which EPA requires health and safety information in fulfilling the purposes of TSCA. The rule requires manufacturers, importers, and processors to submit to EPA copies of unpublished health and safety studies conducted on the substances listed at 40 CFR 716.120. "Health and safety study" is defined generally at 40 CFR 716.3 to include any information or data that relates to, or bears on, the effects of a listed substance on health or the environment. "Copy of study" is defined as "the written presentation of the purpose and methodology of a study and its results.

Under Section 716.3 of the Model Rule, the definition of health and safety study covers "monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture." Thus, monitoring data which fit this description are reportable if they relate to a listed substance and are incorporated in a "copy of study" as defined in the Model Rule.

Generally, under the TSCA section 8(d) Model Health and Safety Data Reporting Rule, the Agency does <u>not</u> require the reporting of raw monitoring data (see, however § 716.40) nor does it require daily or routine monitoring data gathered and examined solely for the purpose of determining compliance with existing regulatory or industry permissible exposure levels. The Agency does require monitoring data which have been analyzed to determine human or environmental exposure to a listed chemical substance when the reports meet the definition of a "health and safety study" found at 40 CFR § 716.3. To further illustrate, specific questions with answers follow:

1. My company measures leaks of a listed substance from valves or other plant equipment by localized sampling devices. Our engineers use the data to evaluate process integrity and determine the need to replace equipment or improve maintenance procedures. Often, our engineers prepare short reports summarizing the results of monitoring and recommending process improvements. Are the data generated from such equipment monitoring reportable under the 8(d) Model Rule?

Answer

No. In this situation, the company is not measuring or assessing the exposure of workers to a listed substance but is monitoring equipment leaks to evaluate the need for process modifications or changes in maintenance procedures.

2. My company conducts monitoring to determine the presence of a listed chemical in areas of our plant where employees could be exposed -- e.g., near storage tanks and loading or unloading equipment. Our industrial hygienists may prepare reports or memos which briefly describe the results of area monitoring and comment on their significance. For example, these reports might identify the monitoring techniques we use, summarize measured values in tabular form and offer limited comments and recommendations (e.g., "reported levels are not of concern," "reactor leaks should be fixed," or "workers should be more careful during loading operations.") Should such reports be submitted under the Section 8(d) Model Rule?

Answer

No. Although the area monitoring data are being used to evaluate workplace exposure, the reports described are too limited in scope for the data to be considered "aggregated and analyzed" as these terms are used in the Model Rule. However, if the area monitoring data are combined with other information/analysis to provide an assessment of employee exposure, a reportable study would exist and Section 8(d) would apply.

3. My company conducts personal monitoring on employees potentially exposed to a listed chemical. The results of this monitoring are entered into a computerized data-base. Our industrial hygienists periodically obtain and review computer printouts of monitoring results. In addition, a computerized summary of the data is occasionally compiled and circulated to our management. This summary does not describe our sampling techniques or present a discussion and analysis of the data. Is our company required to report under Section 8(d)?

Answer

No. Reporting is not required unless monitoring results are incorporated in a "copy of study" as defined in Section 716.3 of the Model Rule. Such a document should contain a description of the methodology, tabulation of the data, and summary and analysis of the results. Monitoring information that does not have these attributes are not reportable under Section 8(d).

4. My company conducts occasional personal monitoring for a small number of employees. Such monitoring may be initiated to verify the effectiveness of engineering controls, to determine the consequences of a reactor leak or upset, or to respond to employee complaints about alleged health effects caused by exposure to a listed chemical. The data resulting from this monitoring are generally incorporated in a brief report. For example, such a report might evaluate measured levels from the standpoint of OSHA permissible exposure levels or voluntary exposure limits set by ACGIH or the company. Comments on the adequacy of personal protective equipment or the effectiveness of engineering controls might also be included. Must such reports be submitted?

Answer

No. Routine personal monitoring data do not have to be submitte if the report merely confirms that permissible exposure levels have or have not been exceeded. Additional comments/recommendations regarding the adequacy of exposure controls do not render the document reportable if the discussion does not include the impact of the controls/lack of controls on the health or safety of the monitored personnel.

If, however, the personal monitoring data are studied and their meaning analyzed and discussed in terms of the impact of the exposures on the employees, the document would then be reportable under the 8(d) Model Rule.

5. At the end of each year, my company prepares a detailed report compiling the results of periodic monitoring throughout the year for a plant where a listed chemical is produced. This report is provided to our corporate industrial hygiene staff and to worker representatives. In the report, the data are analyzed using certain standard statistical methods. For example, we calculate mean and median values and standard deviations using the monitoring data for each identifiable job category. The report also provides a description of exposure conditions at the plant. For example, the manufacturing process for the listed chemical is described and an overview of the employee population at the plant is presented which indicated the number of workers,

the nature of their job assignments and the tasks giving rise to exposure to the listed chemical. Based on this general background, the report discusses the significance of the monitoring data from the standpoint of changes in work practices, differences between job categories, equipment or process modifications, or other variables affecting exposure. Should this report be submitted under Section 8(d)?

Answer

Yes. Such reports would be "health and safety studies" subject to the TSCA Section 8(d) Model Rule. Because the report compiles monitoring data in a form which is aggregated, and then presents an analysis which discusses human exposure, the report would have the attributes of a "health and safety study" and "copy of study" specified in Section 716.3 of the Model Rule.

6. My company has an ongoing employee monitoring program for a listed chemical. We review the monitoring data we generate at regular intervals and often prepare informal management summaries of the data. It is also possible that we will prepare reports which are subject to reporting under Section 8(d) because they include an assessment of employee exposure. We do not, however, know whether such reports will be prepared when we embark upon a monitoring program. Rather, the need for worker exposure assessments will depend on factors which cannot be foreseen in advance. For example, reports of new toxicological studies, rulemaking proposals by EPA or other agencies, or employee complaints may motivate us to conduct an evaluation of worker exposure. In these situations do we have to notify EPA that a "health and safety study" on a listed chemical is being "initiated" under 40 CFR 716.35?

Answer

No. Raw monitoring data and brief summaries of monitoring results are not reportable studies under the Section 8(d) Model Rule. For this reason, companies are not required to notify EPA that they are "initiating" a reportable study when they institute programs of routine employee monitoring during which no assessment of human exposure is planned.

A notice of initiation would have to be submitted to EPA only if the company decides to conduct an assessment of human (or environmental) exposure using the raw monitoring data or expanding on the brief summary of monitoring results. Under Section 716.35 of the Model Rule, this notice must be submitted to EPA within 30 days after the company forms a firm intent to conduct such an assessment and the report itself must be submitted within 30 days of its completion (§ 716.60(b)(2)).

7. Occasionally, my company prepares reports in which exposure levels for a given workforce are directly compared to adverse health effects reported by individual workers. These reports can range from a comprehensive epidemiology study to an investigation of a complaint by a single employee. Should these reports be submitted under the Section 8(d) Model Rule?

Answer

Such reports should be submitted where they contain an assessment of exposure conditions or provide new information about the association between exposure levels and adverse health effects. For example, the definition of "health and safety study" would apply to a report which compiles monitoring data or other exposure information for a particular workforce and then evaluates the relationship between exposure levels and the health status of individual employees. Additional consideration should be given to reporting such findings under TSCA section 8(e), the "substantial risk" reporting provision of TSCA, if the 8(e) reporting obligation is incurred before that of 8(d).

8. My company regularly conducts monitoring to determine ambient air concentrations of listed chemicals near our plant. This monitoring may be conducted at the fence-line of our plant or at monitoring stations in the surrounding community. We conduct this monitoring for a variety of reasons, including compliance with permit limitations imposed under federal or state laws and preparation of community health assessments for substances subject to Title III of SARA. It is our practice to prepare informal reports summarizing the results of this monitoring at regular intervals. These reports describe the locations where we place sampling equipment, tabulate the measurements made during sampling, and briefly discuss the results. This discussion may involve a comparison of the monitoring results to a recognized exposure limit or a simple statement that the results are too low to be of concern. Should such reports be submitted under the 8(d) Model Rule?

Answer

No. Reports which merely summarize the results of environmental monitoring and compare the results to a recognized exposure limit need not be submitted. Additionally, a simple conclusion based on routine monitoring data, such as "the results are too low to be of concern," does not give rise to a reportable study as the conclusion is supported by no rationale/analysis of the results.

9. My company regularly conducts end-of-pipe analyses of plant effluent to determine the concentrations of certain listed chemicals discharged to POTWs. This monitoring is conducted to assure compliance with our NPDES permit under the Clean Water Act. We maintain logbooks which document our determinations and the procedures we employ. Periodically, we prepare a report which summarizes the results of our effluent discharge analysis and determines whether we are in compliance with permit limitations. Should the logbooks and reports be submitted to EPA under Section 8(d)?

Answer

No. The logbook consists of raw monitoring data which is excluded from reporting under EPA's Model Rule. The report is likewise of measurements of the quantities of a listed chemical which are present in plant effluent and are discharged (directly or indirectly) into water bodies outside plant boundaries. Such monitoring data does not indicate "the exposure of humans or the environment" to the listed chemical but merely quantities of the chemical in the plant's waste stream, and is therefore outside the definition of reportable monitoring data in Section 716.3 of the Model Rule.

If, for example, the report was expanded beyond an end-of-pipe assessment to include an assessment of down-stream environmental exposure, the report would then be submittable.

10. Concern has been raised about groundwater contamination in the vicinity of a plant at which my company processes a listed chemical. My company retained a consulting firm to take soil and groundwater samples at several locations and analyze them for the presence of RCRA Appendix IX chemicals, which include substances listed under Section 8(d). The consulting firm prepared a report which described the results of this sampling and analysis. As a result of the consultant's findings, we concluded that no remedial action was warranted. Is such a report a "health and safety study" under section 8(d)?

Answer

No. The report, as described, does not constitute a "health and safety study" because the results of soil and groundwater sampling simply indicate whether a listed chemical is present at the point of sampling. Although the raw environmental monitoring data do reflect environmental exposure at the point of sampling, an analysis of the data and discussion regarding the impact of the substance on the environment should be present in this type

of environmental monitoring report to reach the 8(d) reporting threshold. Even if the report concluded that remedial action wa warranted without discussing the impact/potential impact of the substance on the environment, the reporting threshold would not be reached.

If, however, the monitoring data are analyzed to determine the exposure/potential exposure of a population of an organism to the listed substance, the study would be reportable notwithstanding the fact that the report contained no discussion of effects/impact.

11. My company is one of a group of Potentially Responsible Parties (PRPs) that have agreed to clean up a waste site contaminated with a listed substance that we manufacture. As part of the remediation program, we are participating in a study to determine the degree of contamination at the site. During this study, groundwater and drinking water supplies will be monitored for certain RCRA Appendix IX substances, many of which are also listed under Section 8(d). Based on information about the hydrogeology of the area surrounding the site, this information will be used to assess the long-term risk of drinking water contamination. As part of this assessment, conclusions will be reached about the concentrations of the subject chemicals in the groundwater and in drinking water which nearby communitie might consume and about the resulting potential health impact. Will the report prepared at the conclusion of the study constitute a "health and safety study" under Section 8(d)?

Answer

Yes. In such a report, monitoring data will be used to determine a listed chemical's migration through soil and groundwater and conclusions will be reached about the concentrations of the chemical to which members of surrounding communities might be exposed and the resulting health impact of such exposure. Under these circumstances, the "health and safety study" definition would apply because monitoring data have been "aggregated and analyzed" to measure the exposure of humans to the chemical substance. The initiation of such a study must be reported as specified in § 716.35(a)(2). Upon completion, such a study must be submitted within 30 days per § 716.60(b)(2). It should be noted, however, that per § 716.20(a)(2), certain studies previously submitted to the EPA Office of Toxic Substances are not subject to reporting, and per § 716.20(a)(3), studies previously sent to Federal agencies with no confidentiality claims are subject only to listing requirements (§ 716.35(a)(4)).

Additionally, per § 716.30(b) and § 716.35(b), one person (e.g., a trade association or company) may satisfy the reporting obligations of other persons by identifying the establishment(s) on whose behalf the submission is made. In this manner, certain duplicative reporting may be avoided.

12. Our company is required to conduct biomonitoring periodically on effluent streams pursuant to our Federal NPDES permit and state permit. In a screening test, Daphnids or Mysids are tested for survival by exposure to effluent containing numerous chemicals, presumably including some 8(d) listed chemicals manufactured or processed at the site. Depending on the results of this screening test, an LC_{50} must be determined for the Daphnids or Mysids. In the report describing the results of this biomonitoring, we do not determine the levels at which 8(d) listed chemicals are present in the effluent, nor do we attempt to identify the component of the effluent responsible for any adverse effects on survival. Are reports of such biomonitoring reportable under the TSCA 8(d) rule?

Answer

No. Under 40 C.F.R. § 716.20 (a)(8), reporting is not required for monitoring data on mixtures containing one or more 8(d) listed chemicals where the data are not analyzed to determine the exposure or concentration levels of the listed substance. In addition, EPA does not require the submission under Section 8(d) of the results of routine monitoring conducted for purposes of compliance with permit limits or other regulatory requirements.